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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,134	08/29/2005	Steven Jones	85084-402	3937

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EXAMINER	
HURT, SHARON L	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/522,134	JONES ET AL.	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,13-15,17,19-23 and 25-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-3,5,13-15,17,19-23 and 25-28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *24 Jan 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-6 and 13-28, in the reply filed on August 29, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Amendments to claims 1-2, 5, 13-14, 17, 21-22 and 25 filed on August 29, 2006 are acknowledged. Applicant has cancelled claims 4, 6-12, 16, 18, and 24. Claims 1-3, 5, 13-15, 17, 19-23 and 25-28 are pending and under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 13, 17, 19-21, 25 and 27-28 are rejected under 35 U.S.C. 102(a) as being anticipated by Kahn et al. (Journal of Virology, Nov. 2001, Vol. 75, No. 22, p. 11079-11087).

The claimed invention is drawn to a recombinant vesicular stomatitis virus (VSV) particle comprising a nucleic acid molecule encoding a foreign glycoprotein inserted into

the viral genome wherein the foreign glycoprotein has replaced the native VSV glycoprotein, wherein the first gene of the recombinant VSV codes for the foreign protein.

The claimed invention is also drawn to a method of eliciting an immune response in an individual comprising: administering a recombinant VSV particle comprising a nucleic acid molecule encoding a foreign glycoprotein inserted into the viral genome wherein the foreign glycoprotein has replaced the native VSV glycoprotein, wherein the first gene of the recombinant VSV codes for the foreign protein, wherein the particle is administered orally and/or intranasally.

The claimed invention is also drawn to a method for preparing a pharmaceutical composition for passive immunization of an individual comprising: administering a recombinant VSV particle comprising a nucleic acid molecule encoding a foreign glycoprotein inserted into the viral genome wherein the foreign glycoprotein has replaced the native VSV glycoprotein; harvesting antibodies; and mixing antibodies with a suitable excipient or carrier, thereby forming a pharmaceutical composition, wherein the first gene of the recombinant VSV codes for the foreign protein, wherein the particle is administered orally and/or intranasally.

Kahn et al. teaches a recombinant vesicular stomatitis virus (VSV) expressing foreign proteins that elicit specific protective immunity (Abstract). Kahn teaches the VSV glycoprotein (G) gene was deleted from the full-length cDNA VSV genomic plasmids containing the RSV G gene such that the RSV G genes replaced VSV G in viral genome (page 11081, second column). The RSV G (attachment) is the first and

major antigenic glycoprotein (page 11079, last paragraph). Kahn teaches a method of eliciting an immune response in mice by intranasal vaccination with a recombinant VSV expressing RSV G (Abstract). Kahn teaches about vaccine development and passive immunization with a recombinant VSV expressing RSV G (page 11079, last paragraph). Purified RSV was harvested from baby hamster kidney cells and the antibodies were detected by ELISA after mice were inoculated intranasally with recombinant viruses (page 11080, third paragraph and page 11083, second and third paragraph).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Schnell et al. (Cell, September 1997, Vol. 90, p. 849-857). The claimed invention is drawn to a recombinant vesicular stomatitis virus (VSV) particle comprising a nucleic acid molecule encoding a foreign glycoprotein inserted into the viral genome wherein the foreign glycoprotein has replaced the native VSV glycoprotein.

Schnell et al. teaches about a recombinant vesicular stomatitis virus with a deletion of the glycoprotein and expressing the HIV-1 receptor CD4 and coreceptor CXCR4 which has been substituted for the VSV G gene (page 849, first and fourth paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5, 13-15, 17, 19-23 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kahn et al. (Journal of Virology, Nov. 2001, Vol. 75, No. 22, p. 11079-11087) as applied to claims 1, 5, 13, 17, 19-21, 25 and 27-28 above, in view of Takada et al. (Proceedings of the National Academy of Sciences of the United States of America, December 1997, Vol. 94. pp. 14764-14769).

The claimed invention as described above wherein recombinant VSV particle and methods for eliciting and immune response and preparing a pharmaceutical composition have a foreign glycoprotein of a viral hemorrhagic fever glycoprotein or an immunogenic fragment thereof, wherein the viral hemorrhagic fever glycoprotein is from Lassa virus, Marburg virus, Ebola virus, Crimean-Congo HFV, Dengue virus, Nipah virus, Hendra virus, Machupo virus, Junin virus, Guanarito virus or Sabia virus.

The teachings of Kahn et al are described above. Kahn does not teach substitution of the VSV glycoprotein with the glycoprotein of a hemorrhagic fever virus.

Takada et al. teaches about Ebola virus glycoprotein incorporated into VSV particles (Abstract). Takada also teaches that VSV has been used as a model system for studying the replication of RNA viruses and its use as a vector to express foreign proteins (page 14764, second column, first full paragraph).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to insert the glycoprotein of a different virus into recombinant VSV. Takada demonstrated how the glycoprotein can be manipulated to

allow safe investigations of Ebola virus binding and fusion to the cell membrane (page 14768, Discussion first paragraph). More importantly, it could obviate the need for *in vitro* cultivation and biosafety level 4 containment in studies to analyze the membrane proteins of highly pathogenic viruses and those incapable of being cultures in vitro (page 14768, last paragraph). The person of ordinary skill in the art would have been motivated to make that (those) modification(s) because Kahn teaches recombinant VSV expressing influenza and measles virus (page 11080, first paragraph) in addition to RSV, and reasonably would have expected success because of the teachings of Kahn and Takada.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Roberts et al. (Journal of Virology, May 1999, Vol. 73, No. 5, pages 3723-3732) teaches about an intranasal vaccine where the vesicular stomatitis virus (VSV) glycoprotein is deleted and expresses influenza virus (Abstract).

Pushko et al. (Vaccine, August 2000, Vol. 19. No. 1, pages 142-153) teaches about a vaccine where Ebola glycoprotein genes were introduced into the Venezuelan equine encephalitis (VEE) RNA in place of the VEE structural protein genes (Abstract).

Pushko et al. (Journal of Virology, December 2001, Vol. 75. No. 23, pages 11677-11685) teaches about a vaccine for Lassa virus and a bivalent vaccine for Lassa and Ebola viruses that are based on an RNA replicon vector derived from an attenuated strain of Venezuelan equine encephalitis expressing the glycoprotein genes of both viruses (Abstract).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt
25 September 2006

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